COVID-19 Vaccine

Administration Errors Revaccination Guidance

A vaccine administration error is any preventable event that may cause or lead to inappropriate use of vaccine or patient harm. When an error occurs with a COVID-19 vaccine, follow the revaccination guidance in the table below, using an age-appropriate COVID-19 vaccine and formulation. Then continue with the recommended schedule of subsequent dose(s) unless otherwise noted (see footnotes).

For all vaccine administration errors:

- Inform the recipient of the vaccine administration error.
- Consult with the state immunization program and/or immunization information system (IIS) to determine how the dose should be entered into the IIS, both as an administered dose and to account for inventory.
- Follow the revaccination guidance below, using an age-appropriate COVID-19 vaccine and formulation. Continue with the recommended schedule of subsequent dose(s) unless otherwise noted.
  - For doses recommended to be repeated, consider delaying the repeat dose for 8 weeks after the invalid dose based on the potential for increased reactogenicity and the rare risk of myocarditis from mRNA COVID-19 vaccines, particularly among males 12-29 years of age.
- The recommendations apply to all FDA-approved or FDA-authorized COVID-19 vaccines and all doses unless otherwise stated.
- Providers are required to report all COVID-19 vaccine administration errors—even those not associated with an adverse event—to VAERS (https://vaers.hhs.gov/).
- Determine how the error occurred and implement strategies to prevent it from happening again.

For more detailed information on COVID-19 errors, see: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Appendix-A

Interim Revaccination Guidance

Type	Administration error/deviation	Do NOT repeat dose	Repeat dose immediately	Repeat dose after invalid dose by the minimum interval*	Contact manufacturer
Site/route	Incorrect site (i.e., site other than deltoid or anterolateral thigh)	✓			
	Incorrect route (e.g., subcutaneous)	✓			
Age	Administered to an unauthorized age group†	✓			
Formulation or dosage	Pfizer-BioNTech 12 years of age or older formulation (purple or gray cap) administered to a child age 5 through 11 years‡§¶	✓			
	Pfizer-BioNTech 5–11 formulation (orange cap) administered to a person age 12 through 17 years‡¶	✓			
	Pfizer-BioNTech 5–11 formulation (orange cap) administered to a person 18 years or older		✓		
	Higher-than authorized dose (volume) of the correct formulation administered§	✓			
	Lower-than authorized or unknown dose (volume) of the correct formulation administered		✓		

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Type	Administration error/deviation	Do NOT repeat dose	Repeat dose immediately	Repeat dose after invalid dose by the minimum interval*	Contact manufacturer
Storage and handling	Dose administered after improper storage and handling (i.e., temperature excursion)**				✓
	Dose administered past the expiration or beyond-use date**				✓
Intervals	mRNA primary series or additional dose administered **prior to** the recommended interval*			✓	
	Any COVID-19 vaccine dose administered at any interval **after** the recommended interval††	✓			
	Booster dose administered prior to the recommended interval	✓			
	Tixagevimab/cilgavimab (EVUSHELD)™ administered less than 14 days after COVID-19 vaccination††	✓			
Mixed series	Incorrect mRNA COVID-19 product inadvertently administered for the 2nd dose in the primary series	✓			
Diluent (Pfizer-BioNTech only)	Only diluent is administered		✓		
	Pfizer-BioNTech is mixed with too much diluent		✓		
	Pfizer-BioNTech is mixed with too little or no diluent§	✓			
	Any incorrect diluent is used (anything other than 0.9% sodium chloride [normal saline, preservative-free])**				✓

* Vaccine administered up to 4 days before the minimum interval may be counted and do not need to be repeated

† If any COVID-19 vaccine is administered before age 5 years, do not give another dose at this time. If a vaccine other than Pfizer-BioNTech is given to a person under age 18 years:

- If age 5–17 years and Moderna was given in error, consider the age-appropriate Pfizer-BioNTech formulation as the second dose (based on the recipient's age on the day of vaccination) at least 28 days after the Moderna dose. If Moderna was given as the second dose, (or 3rd dose for moderately or severely immunocompromised persons), series is complete.
- If age 5–17 years and Janssen was given, consider a single dose of the age-appropriate Pfizer-BioNTech formulation (based on the recipient's age on the day of vaccination) at least 2 months after Janssen.

‡ In general, do not repeat dose. However, a repeat dose of the age-appropriate formulation may be administered based on clinical judgement at an interval of 21 days after the dose given in error if:

- 0.1 mL of the Pfizer-BioNTech purple cap formulation is administered to a child age 5 through 11 years
- A lower-than-authorized dose from the Pfizer-BioNTech orange cap formulation is administered to an adolescent age 12 through 17 years

§ If the administration error resulted in a higher-than-authorized vaccine dose, in general the second dose may still be administered at the recommended interval. However, if local or systemic side effects following vaccination are clinically concerning (outside of the expected side effect profile), lead to serious adverse reactions, or are ongoing at the time of the second dose, the decision to administer the second dose may be assessed on a case-by-case basis.

¶ Individuals who will turn from 11 to 12 years of age between their first and second dose in the primary regimen may receive either Pfizer-BioNTech COVID-19 Vaccine formulation in the authorized dosage. This is not considered an error and VAERS reporting is not indicated.

** Contact the manufacturer for information on the stability of the vaccine. If the manufacturer does not have information to support the stability of the vaccine, repeat the dose immediately (no minimum interval).

†† In general, do not repeat dose. However, based on clinical judgment, a repeat dose of vaccine may be administered at an interval of at least 28 days after the dose of vaccine.